Proposed Amendment of
10A NCAC 26E .0603
Requirements for Transmission of Data

Agency: DHHS/ Mental Health, Developmental Disabilities, and Substance Abuse Services

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Impact:

State government:	Yes
Local government:	No
Substantial impact:	No
Federal government:	No
Small businesses:	Yes

Authority: Session Law 2009-438 (Senate Bill 628), §90-113.73(b), §90-113.76

I. Overview

It is proposed that the rule be amended by the Commission to comply with a legislative mandate contained in Session Law 2009-438 (Senate Bill 628), that changes the reporting requirements of pharmacies dispensing controlled substances. Prior to Session Law 2009-438, pharmacies reported dispensing of any prescription twice per month; the law now requires pharmacies to report such distributions within seven days of dispensing the prescription.

II. Rationale for the Proposed Rule

N.C.G.S. §90-113.76 grants the Commission authority to adopt rules necessary to implement the reporting section of the statute, known as the North Carolina Controlled Substances Reporting System Act. Originally, the statute called for dispensers of controlled substances to report data to the Controlled Substances Reporting System on a monthly for the first 12 months and twice monthly after this period. The Commission adopted rules to require that this data transmission occur on the 15th and 30th of each month.

Session Law 2009-438 requires pharmacies to report data to the Controlled Substances Reporting System (CSRS) no later than seven days after the prescription is dispensed. This change brings the CSRS into compliance with the National All Schedules Prescription Electronic Reporting Act guidelines, which are set by the federal Department of Health and Human Services. More importantly, the statutory change provides more current information to practitioners using the system to assist them in providing care for their patients.

The proposed amendment is necessary to conform to the statutory mandate. In addition, the proposed language allows for flexibility within the rule should there be additional changes in reporting timeframes in future legislation.

III. Action Requested

The proposed amendment (see rule text in Appendix 1) is presented to the Commission for approval for the North Carolina Administrative Code.

IV. Analysis of Fiscal Impact

The amendment to Rule 10A NCAC 26E .0603 has been proposed to eliminate a reporting conflict between the General Statutes and Administrative Code brought about by the passage of Session Law 2009-438 (Senate Bill 628). Amending Rule 10A NCAC 26E .0603 will result in pharmacies being required to report data to the Controlled Substance Reporting System ("CSRS") within 7 days of the dispensing of a prescription. Thus, instead of reporting twice per month, as set forth in current rule language, pharmacies will be required to report weekly. It is important to note that as of January 2, 2010, pharmacies are required to report within 7 days pursuant to Session Law 2009-438.

Pharmacy sub-systems that generate 128 bit encrypted file to send in ASAP format via FTP to the Controlled Substance database, will need to have sub-system job batch run cycles amended to comply with the needed weekly extract. This should be a relatively low level task in amending programming jobs to run weekly, rather than bi-monthly; but obtaining experienced staff familiar with each subsystem could be expensive for smaller pharmacies with packaged software that would require outside programmers to fix.

State Impact

These changes have already occurred with the 11 pharmacies run by the state with minimal costs. The costs incurred by the eleven state run facilities were $480 per site for a total of $5,280. The state will not incur any additional expense from its contracted vendor, Health Information Designs, Inc. in Auburn, Alabama, due to this change. This is because the volume of reporting will not change, only the frequency.

The DHHS Drug Control Unit ("DCU") who administers the program will not experience any additional costs as the volume of prescriptions is not increasing overall and all data viewed by DCU is viewed online. It is possible increased reports of non-compliant pharmacies from practitioners may come to the attention of the DCU until the change is fully implemented. The only cost anticipated is that DCU staff may spend more time reviewing the data; however, it should be noted that this review is part of their regular duties.

Private Sector Impact

Spread out over 1,400 pharmacies the cost per pharmacy is minimal. Many of the large chain pharmacies account for approximately 78 % of the reporting pharmacies in North Carolina. Some of these are currently already reporting in to North Carolina on a weekly basis or more often. Of those that are not already following this weekly reporting procedure, it is estimated that setting up the mechanism to automatically electronically report on a weekly basis will require between 5 hours and 2 days of one time programming and data testing costs per major chain. There are 16 chain pharmacies (defined as pharmacies that have two or more locations) in the state. Assuming that the chains also incurred the same costs as the State in making this change, then the Division anticipates that they paid $480 each, with a total cost of $7,680.

A majority of independent pharmacies are reporting electronically to the system. Data is entered into their billing system when the prescription is dispensed and is then automatically available for transmission to the Database according to a program they establish. Reports to the database utilize the same reporting format (ASAP 1995) as that used for billing. Many of them use a common vendor to handle their electronic billing and reporting. Therefore one impact is the amount of time required for those pharmacies reporting electronically to increase their reporting from twice per month to weekly. The costs should be minimal as a central programmer can change the report generation information to affect all data reporting for the pharmacies that link to their subsystem. These programmers would costs substantially less per hour and be able to effectively make changes to integrated subsystems quickly and with far less cost than smaller pharmacies requiring contract with outside programmers. According to DMH/DD/SAS staff who are project managers for other division programming contracts, it is not unreasonable to expect this will take 2-8hrs to complete for an experienced programmer (this would private costs in line with the costs incurred in changing state run pharmacy subsystems). An experienced programmer's hourly bill rate averages $120 per hour to make necessary changes. For the approximately 308 independent pharmacies, costs could vary from the low end of the range (2hrs) of $73,920 to $295,680 if the programming took the maximum of 8 hrs.

If a pharmacy does not file electronically, they may file via a disk or paper form, which is then mailed to the state's contracted vendor. There are a small number of pharmacies (less than 10 % of about 1,400 pharmacies in NC) reporting into the system via a mailed disk. Less than 1% of all pharmacies currently report to the system via paper forms. Pharmacies reporting via disk will need to run their report weekly. While the volume of prescriptions reported will not increase, the number of reports they submit will more than double from 24 to 52 reports, and the mailing costs of mailing a disk will double for those pharmacies. The same is true for the pharmacies that report via paper forms; again, this is a very small percentage of pharmacies across the state. There are approximately 140 pharmacies that mail media, and that multiplied by the USPS media rate of $2.38 per envelope that would cost these pharmacies an additional $9,330 in postage fees. For those pharmacies that are mailing in hard copy reports (less than 1%), their costs would be minimal as the number of pharmacies affected by the 1st class envelope mailing rate of $2.24 (9 oz. limit) would create an additional cost of $878 incurred by these

pharmacies to increase reports from 24 to 52 per year. Please note that these cost estimates are without additional services by USPS that pharmacies might desire such as delivery confirmation or Express mail. These costs could add an additional $3,000-$9,000 depending on additional features desired by the pharmacies. Additional staff time charges for shipping preparation would be minimal and should not require additional staff to be hired by pharmacies to prepare and mail shipments of data. Additionally, future mailing costs have not been adjusted for inflation. Total cost estimate for small pharmacies is about $16,208 to be incurred annually.

The costs pharmacies will incur from changing the frequency of reporting might be passed on to the consumers. While it is hard to say what the impact would be, given that pharmacies are facing a one-time cost, and given the number of prescriptions filled monthly, the impact on the consumer would likely be minimal.

Federal Impact: None

State Impact: $5,280

Private Impact: one-time cost of about $82,000-$303,000, plus an annual cost of about $13,000-$19,000

Substantial Economic Impact: None

Appendix 1

10A NCAC 26E .0603 is proposed for amendment as follows:

10A NCAC 26E .0603 REQUIREMENTS FOR TRANSMISSION OF DATA

(a) Each dispenser shall transmit to the Department the data as set forth in G.S. 90-113.73. The data shall be transmitted in the ASAP Telecommunication Format for Controlled Substances, published by the American Society for Automation in Pharmacy that is in use in the majority of states operating a controlled substance reporting system.

(b) The dispenser shall transmit the data electronically unless the Department approves a request for submission on paper as set forth in Paragraphs (e) and (f) of this Rule.

(c) The dispenser's electronic transfer data equipment including hardware, software and internet connections shall be in compliance with the Health Insurance Portability and Accountability Act as set forth in 45 CFR, Part 164.

(d) Each electronic transmission shall meet data protection requirements as follows:

(1) Data shall be at least 128B encryption in transmission and at rest; or

(2) Data shall be transmitted via secure file transfer protocol. Once received, data at rest shall be encrypted.

(e) The data may be submitted on paper, if the dispenser submits a written request to the Department and receives prior approval.

(f) The Department shall consider the following in granting approval of the request:

(1) The dispenser does not have a computerized record keeping system.

(2) The dispenser is unable to conform to the submission format required by the database administrator without incurring undue financial hardship.

(g) The dispenser shall report the data ~~on the 30th day of each month for the first 12 months of the system's operation, and on the 15th day and 30th day of each month thereafter. If the 15th or the 30th day does not fall on a business day the dispenser shall report the data on the next following business day.~~ pursuant to the requirements of G.S. 90-113.73(a).

(h) The Department shall provide reports to the Commission concerning the outcomes of the implementation of the controlled substances reporting system. The reports shall be made to the Commission six and 12 months after the reporting system is implemented.

History Note: *Authority G.S. 90-113.70; 90-113.73; 90-113.76;*
Temporary Adoption Eff. January 1, 2007;
Eff. April 1, 2007.
Amended Eff. – 1, 2010.